Written Statement

OF

Douglas A. Beigel,

COLA

ON THE

"CLINICAL LAB QUALITY:

OVERSIGHT WEAKNESSES UNDERMINE FEDERAL

STANDARDS"

SUBCOMMITTEE ON CRIMINAL JUSTICE,

DRUG POLICY AND HUMAN RESOURCES

COMMITTEE ON GOVERNMENT REFORM

UNITED STATES HOUSE OF REPRESENTATIVES

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Mr. Chairman and Members of the Committee:

I am Douglas Beigel, Chief Executive Officer of COLA, a non-profit organization whose purpose is to promote excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation.

COLA appreciates the opportunity to speak to you today about the findings and recommendations contained in the upcoming GAO report titled "CLINICAL LAB QUALITY: CMS and Survey Organization Oversight Should be Strengthened (GAO-06-

416)". This hearing and the GAO report on which we are commenting are significant and timely examinations of this important public service.

COLA was conceived by a number of very prominent medical associations including the American Academy of Family Physicians, the American Society of Internal Medicine (now the American College of Physicians), and the American Medical Association in 1985 and was incorporated in May of 1988. COLA's original constituency was quite unique. We served a laboratory community that was largely unregulated, but served an important clinical purpose. The physician office laboratory community produces laboratory results to support their own clinical decision-making.

The COLA accreditation standards and methodology were developed by internists, family physicians and pathologists to be practical and meaningful to the laboratory. The requirements have a positive and immediate impact on patient care.

The standards require that the laboratory director select the proper space, facilities, instrumentation, and personnel to provide prompt and accurate reports of results. There must be a quality assurance program in place that contains a quality control program; participation in Proficiency Testing; an instrument maintenance program; continuing education for staff; and documentation of laboratory activities.

Laboratories are evaluated against these standards using a detailed self-inspection checklist; an extensive personnel report form that describes personnel responsibilities

and training; successful participation in proficiency testing; and comprehensive, system-oriented on-site inspection of laboratory facilities.

I would like to emphasize that every laboratory participating in the COLA program has its Proficiency Testing results reviewed by COLA staff after every event. COLA continually monitors laboratory PT performance and, when performance is failing, we counsel laboratories on fixing the problems—and as appropriate, we do require laboratories to cease testing problem analytes or specialties.

In 1991, COLA accredited some 1336 laboratories. In four short years, laboratory enrollment had grown over 400%-- mostly in response to the newly promulgated CLIA regulations which required regular oversight of all laboratories. Many of our client laboratories were reluctant. Our challenge was to make these laboratories first understand what was important, and second to understand how to do it.

We currently accredit 7200 laboratories in 50 states as well as some international labs. We field 16 surveyors who survey an average of 200 laboratories per year, per surveyor. It is important to note that all COLA surveyors are employees of COLA. COLA does not run a Proficiency Testing program and does not operate a consulting service.

Again, I thank you for inviting me here today and I want to tell you that this is a real opportunity for COLA and others to more closely study the issues. Clearly, patient safety is a driving force as amplified by some highly publicized breakdowns. A number of improvement mechanisms have been suggested, including those by Representative Cummings. We have heard you and we are studying the issues. We are in the quality improvement business and we expect our clients and ourselves to commit to continuous quality improvement. We are improving everyday. We are looking at ways to instill continual readiness in all our laboratories. However, we must be vigilant to ensure that we do not disrupt patient care and that we maintain convenient access to critical laboratory services.

During the course of this study, we responded to numerous written and verbal inquiries from the GAO and performed several in-depth data analyses. As COLA assisted the GAO in this effort, we welcomed the critical, but focused examination of CLIA oversight, and we used the process to discover opportunities to improve our accreditation program. We believe that the GAO did an admirable job in performing this complex assignment. We think that GAO staff will acknowledge this difficulty in assessing such a unique public/private partnership. I am pleased to share with you that we agree with a number of the GAO's finding and recommendations and I look forward to discussing those with you now. I will also touch on a few areas of the report that we found troubling. This report reinforces and validates for COLA many of the guiding principles

that were used to design the most widely used laboratory accreditation program in the United States.

Agreement

As I noted, we agree with a number of the GAO's findings and recommendations. It was not difficult to find agreement, as COLA has employed these recommendations for years.

We wholeheartedly agree that education to improve lab quality should not preclude the identification and reporting of deficiencies that affect lab testing quality. We also believe that phase-in requirements are absolutely appropriate.

Education is a critical component to the reasonable and appropriate implementation and enforcement of laboratory performance requirements. COLA believes that such an educational approach is essential to the desired outcome of real improvement in laboratory performance and to prevent the continuation of deficiencies across inspection cycles. Education is essential to the improvement process as it empowers laboratories to meet or exceed the minimum expectations. COLA takes its enforcement responsibilities very seriously, and we are proud of our consistent track record in the appropriate enforcement of CLIA. The GAO is absolutely correct that COLA begins educating laboratories upon enrollment in our accreditation program. This approach

yields meaningful improvement-based interactions with our accredited laboratories over the course of their two-year accreditation period. The onsite inspection is but one aspect of the program. As we described to the GAO during the course of its examination, we continually monitor laboratory performance on Proficiency Testing, and we regularly communicate with and educate laboratories—before and after an onsite survey.

COLA's comprehensive surveyor training program, in conjunction with individual surveyor exposure to hundreds of laboratories yearly, provides the COLA surveyors with a unique opportunity to share their knowledge and experience during a laboratory's onsite survey. It has always been the goal of COLA's Accreditation program to bring laboratories, particularly the smaller Physician Office Laboratory with its less experienced staff, into compliance with the law by a combination of approaches that identifies the deficiencies present and shares with the lab the correct way to assure quality patient testing. COLA then follows up on the identified deficiencies and requires an evidence-based response from the laboratory before their accreditation is approved or continued. COLA cites ALL problems in the lab.

COLA exists to help improve laboratory medicine and patient care- the primary tenets of which are lasting improvement mechanisms and quality systems generated by committed, informed, and prepared laboratory directors and staff. CLIA’s intent is to improve the quality of laboratory testing. As new technologies emerge and laboratory

testing evolves, it is more important than ever that the industry understands the principles of quality laboratory testing and apply them correctly.

We agree that laboratories should provide lab workers with instructions on how to file anonymous complaints—and that as an approved survey organization, we expect laboratories to act accordingly.

COLA takes complaints very seriously and actively investigates all complaints. We require laboratories to post instructions to lab workers on how to file an anonymous complaint. However, we do not think that simply knowing how to file an anonymous complaint is THE single solution for bringing laboratory problems to light. We require laboratories to have their own protocols for handling problem issues and we encourage laboratory leadership to solicit input from personnel.

We agree that unannounced inspections in the smaller lab are disruptive and unworkable.

The GAO is correct in concluding that unannounced inspections for the smaller lab would not be appropriate. Because these labs are so small and because the medical and laboratory directors often wear many hats, arriving unanounced causes disruption of the laboratory work which in turn reduces the quality of patient care. Also, because

personnel vital to an inspection process may not be present when inspectors arrive, many inspections would have to be postponed and rescheduled. This would undoubtedly contribute to increased costs for accreditation services to labs.

We agree that CMS should be adequately resourced and organized so that it can review and approve survey organization programs in a timely manner.

We have long appreciated the dedication and commitment of CMS staff with whom we have worked so closely over the years. Since 1992, we have spent nearly ten years (off and on) in approval or re-approval discussions. Because we do not implement new requirements prior to CMS approval, these delays can have a significant negative impact on survey organization flexibility. We agree that where possible, CMS should make whatever structural changes necessary to ensure that survey organization programs and requirements are approved expeditiously and always prior to the expiration date of current approval. We look forward to working with CMS to improve this process.

And most importantly, we agree with the assertion that survey organizations (including CMS) should employ trained surveyors and assessors who perform consistent surveys.

The report specifically mentions surveyor training and consistency of assessments as key factors to a strengthened laboratory oversight system. COLA is proud of its significant and extensive surveyor training program and our high level of inter-rater reliability.

When CLIA was enacted, there were many problems that have since been rectified. COLA, as the first CLIA-approved accrediting organization, was designed to promote quality improvement and excellent patient care through an interactive approach, effective enforcement, oversight and education. When the CLIA regulations were promulgated, many laboratories were unfamiliar with the concepts of "quality assurance," "quality control," and "proficiency testing." We committed ourselves to a program of comprehensive surveyor training, coupled with consistent, efficient survey methodologies to instill a culture of quality in our accredited laboratories. COLA's surveyors, all of whom are employed by COLA, are cross trained in multiple laboratory disciplines, quality systems, and more importantly, communications, conflict management, investigation, and root cause analysis techniques.

We utilize results of validation surveys to see how the citations given by our surveyor match those given by another. We look for patterns in these validations that may indicate weakness in a particular area.

Again, we agree with these finding and recommendations and are proud that the GAO recognized these items (already implemented by COLA) as best practices for the industry.

Disagreement

However, as we noted in our comments on the GAO report itself, while the GAO argues that data on laboratory improvement are misleading, we are confident that laboratory quality has improved since the promulgation of CLIA regulations in 1992. Also we disagree with any suggestion that education and enforcement are mutually exclusive. We feel that enforcement can successfully be coupled with education so that laboratories can learn what tools they need for compliance. Furthermore, the GAO's findings draw conclusions regarding notice for onsite inspections and overall laboratory preparedness that run contrary to a quality improvement philosophy. For this reason, COLA has expressed to the GAO and others serious reservations over the use of unannounced laboratory inspections—especially in the smaller laboratory environment.

Laboratory Quality has Indeed Improved

We disagree with the GAO's assertion that laboratory quality may not have improved. COLA now accredits more laboratories than it has in the past 10 years. We are

delighted to see our roles of accredited laboratories filled by conscientious, quality-minded laboratories.

Data that COLA provided the GAO (but not used in the draft report) show that, in general, condition-level deficiencies declined in laboratories that have been surveyed over multiple years. We view this as evidence that the quality of laboratories subject to continual and regular oversight has improved.

We were disappointed that the GAO seemingly discounted the improved Proficiency Testing performance by COLA-accredited laboratories and further intimated that overall laboratory quality has not improved. The percentage of COLA laboratories that fail PT has decreased. COLA is vigilant in the continual monitoring of Proficiency Testing performance by our laboratories. We educate laboratories on how to remedy Proficiency Testing problems and ultimately on how to ensure that all tests are performed in a controlled and analytically sound fashion. COLA is proud of the fact that our program is having a positive impact on laboratories and on patient care.

Education should not be confused with lack of accountability

We disagree with the GAO's assertion that education and enforcement are mutually exclusive. While COLA laboratory inspections are highly educational, we enforce 100% of our [CMS-approved] accreditation requirements]. Many federal requirements in many

regulated industries are “phased-in” in order to allow regulated entities the time to understand and effectively implement the requirements. There is little benefit to the laboratory and no benefit to public health and safety for the establishment of expectations that laboratories cannot meet.

Laboratory Preparation

We disagree with the GAO’s assertion that allowing a laboratory to prepare for a survey masks the discovery of laboratory problems. We know of no research that would support such a conclusion.

While much of a laboratory's evidence of compliance is documentary, there is little of this evidence that can be fabricated in a short period of time. More importantly, I believe the vast majority of laboratory professionals are dedicated to providing the highest quality patient care possible and therefore would not falsify records. Personnel qualifications, root cause analyses of “out of limit” Quality Control (QC), failed Proficiency Testing, the release of patient results when QC is out of limits, incorrect frequency of Quality Control, the use of expired reagents, proper specimen identification, proper report elements - are all virtually impossible to create retrospectively after a survey is scheduled.

Clearly, laboratories that “fix” or complete records immediately prior to an announced onsite inspection (an example used in the GAO report) have critical management and

laboratory operations issues. Our surveyors are trained to spot these problems as well as others that may arise when a laboratory attempts to "fix" documents or data just before an onsite survey.

Documentation is only one part of the onsite assessment. The qualitative, interactive assessment of the laboratory, coupled with the ongoing participation in proficiency testing, provides COLA with a more accurate picture of the overall quality of the laboratory.

Conclusions

To conclude, as we noted in our comments to the GAO, we are very pleased with the many accomplishments of the CLIA program and COLA's accreditation program in particular in improving laboratory quality over the years. Generally, quality of laboratory testing can be measured in two ways: 1) by evaluating quality of laboratories and providing resources to assist them to correct deficient practices; and 2) by preventing laboratories that do not meet quality standards from continuing to provide clinical laboratory testing. We are appropriately achieving these outcomes.

In the past few years we have:

- Invested in an industry-leading Enterprise Information Technology platform that we are confident will further improve laboratory oversight operations as well as individual laboratory efficiency.

- Worked to establish new accreditation requirements that raise the bar.
- Challenged laboratory directors to be more involved.
- Enhanced our industry-leading surveyor training program. COLA's employee surveyors participate in three weeks of continuing education on technical issues, survey and investigative techniques, and communication skills each year.

We have seen improvement and are proud of the strides we have made, but that doesn't mean that we don't look ahead and raise the bar. Our paramount concern is the provision of excellent patient care through meaningful standards and quality improvements.

Thank you for inviting me to share my insights today. I look forward to your questions.